INTEGRA - ACELL(COLUMBIA) UNKNOWN MICROMATRIX

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Catalog Number XXX ¿ MICROMATRIX

Device Problem Adverse Event Without Identified Device or Use Problem (2993)

Patient Problems Pain (1994); Skin Infection (4544)

Event Type Injury

Manufacturer Narrative

An investigation has been initiated based on the reported information.Upon completion of the investigation, a follow-up report will be submitted.

Event Description

A patient reported infection on the forehead with the use of micromatrix internally (nasal cavity septum): a (b)(6) yo caucasian male with preexisting condition of "empty nose symptom", was injected with acell prp and adipose (stem cell) into nasal septum under local anesthesia on (b)(6) 2021.Lot or serial number is unknown.Immediately after injection, patient experienced minor headache(frontal).On (b)(6) 2021 patient continued with frontal pain which became worse and bump on forehead and patient went to physician¿s office.Dr.Prescribed antibiotic.Patient was still experiencing pain and approximately 3 weeks after injection of acell, physician performed urgent sinus surgery to drain and remove infection from septum.Next day, patient was prescribed methylprednisolone to reduce inflammation.Infection was determined to be staph.Patient was treated with cipro (stopped using due to thyroid problem).Augmentin and prednisone, were other medications administered.Patient is still on levoquin.

Manufacturer Narrative

Micromatrix was not returned for evaluation (resorbable product).Additional information received from the customer, indicated the device (a powder) was hydrated or reconstituted with prp and adipose fat (stem cell) for the doctor to be able to inject the reconstituted product inside the nasal cavity of the patient.The micromatrix is not intended for use in empty nose symptom and should not be reconstituted with prp and adipose fat (stem cell).As product reference no, lot number and serial number are not available, a comprehensive review of manufacturing records (dhr) was not possible.However, every micromatrix lot is manufactured following stringent validated processes under class 7 clean room conditions and is sterilized to sal10-6 using electron beam irradiation sterilization process.Furthermore, all lots of micro matrix devices are also tested for endotoxin three times, immediately following disinfection, in-process and final device lot release testing (after sterilization).Integra/ acell endotoxin specification is established as per usp <161>.Any lot not meeting the endotoxin specification the entire lot is immediately rejected and scrapped.Root cause is undetermined.With the information provided by the complainant thus far, a definitive source or cause of infection cannot be established.Micromatrix is not recommended to be reconstituted with prp and adipose fat (stem cell), and also is not recommended to be used for empty nose symptom which is deemed a modification to the product and an off-label use.It is also unknown if the doctor shared the content of one vial of micromatrix with more than one patient.As per ifu, the device is intended for one-time use.In addition, it is also unknown how the device (a powder) was hydrated or reconstituted with prp and adipose fat (stem cell) for the doctor to be able to inject the reconstituted micromatrix inside the nasal cavity of the patient.Unknown if the reconstitution process was aseptic.

Event Description

N/a.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name	UNKNOWN MICROMATRIX
Type of Device	MICROMATRIX
Manufacturer *(Section D)*	INTEGRA - ACELL(COLUMBIA) 6640 Eli Whitney Drive 6640 Eli Whitney Drive Columbia MD
Manufacturer *(Section G)*	INTEGRA - ACELL(COLUMBIA) 6640 Eli Whitney Drive Columbia MD

Manufacturer Contact	Vivian Nelson 1100 Campus Drive Princeton, NJ 6099362319
MDR Report Key	12664980
MDR Text Key	277382015
Report Number	3005920706-2021-00003
Device Sequence Number	1
Product Code	KGN
Combination Product (y/n)	N
PMA/PMN Number	K172399
Number of Events Reported	1
Summary Report (Y/N)	N
Report Source	Manufacturer
Source Type	User Facility,Company Representative
Reporter Occupation	Other
Type of Report	Initial,Followup
Report Date	11/22/2021
***1* Device was Involved in the Event**	
***1* Patient was Involved in the Event**	
Is this an Adverse Event Report?	Yes
Is this a Product Problem Report?	No
Device Operator	Health Professional
Device Catalogue Number	XXX ¿ MICROMATRIX
Was Device Available for Evaluation?	No
Is the Reporter a Health Professional?	No
Initial Date Manufacturer Received	09/21/2021
Initial Date FDA Received	10/20/2021
Supplement Dates Manufacturer Received	11/03/2021
Supplement Dates FDA Received	11/22/2021
Is the Device Single Use?	Yes
Is This a Reprocessed and Reused Single-Use Device?	No
Type of Device Usage	Unknown
Patient Sequence Number	1
Patient Age	37 YR
Patient Sex	Male

ACELL, INC. MICROMATRIX Back to Search Results

Model Number MICROMATRIX

Device Problems Off-Label Use (1494); Improper or Incorrect Procedure or Method (2017)

Patient Problems High Blood Pressure/ Hypertension (1908); Itching Sensation (1943); Dizziness (2194); Weight Changes (2607); Unspecified Nervous System Problem (4426); Unspecified Heart Problem (4454); Unspecified Gastrointestinal Problem (4491)

Event Date 10/16/2020

Event Type Injury

Manufacturer Narrative

This mdr is being submitted because of a reported adverse event after initial application of the acell device.The use of micromatrix for this type of treatment is off label and not recommended or promoted by integra/ acell.Review of micromatrix ifu lbl-1001.02 showed that its indication of use does not include treatment of (nasal) dryness.Furthermore, ifu instruction also did not include hydrating micromatrix with prp for any application.We believe the reported aes are likely a result of past medical history and have no reason to suspect they are directly related to device use, but are filing the mdr as a conservative measure until receiving additional information from the patient or health care provider.

Event Description

Integra/ acell received a fda letter related to a medwatch report submitted by a patient alleging adverse event after using micromatrix.Mdr no: mw5101077, mdr date: 30-apr-2021, patient alleged that he went to an ent specialist because of some dryness issue and the doctor mixed micromatrix with prp and injected the mixture in his turbinates.Patient claimed that since the treatment, he is suffering from heart discomfort, dysautonomia, dizziness, gi disturbances and itching.Patient also claimed previous testing showed dysautonomia, hypertension (previously he had consistent low bp) and weight gain.

Manufacturer Narrative

This mdr is being submitted because of a reported adverse event after initial application of the acell device.Review of micromatrix ifu lbl-1001.02 showed that its indication of use does not include treatment of dry nose syndrome or rhinitis.Furthermore, ifu instruction also did not include hydrating micromatrix with prp for any application.The use of micromatrix for this type of treatment is off label and not recommended or promoted by integra/ acell.Integra/acell is not aware of any clinical evidence that evaluates the use of micromatrix for this type of procedure.We believe the reported aes are likely a result of past medical history and have no reason to suspect they are directly related to device use, but are filing the mdr as a conservative measure until receiving additional information from the patient or health care provider.This follow-up report includes additional data received from the complainant after a phone conversation between integra/ acell and the complainant on june 18, 2021.

Event Description

Integra/ acell received a fda letter related to a medwatch report submitted by a patient alleging adverse event after micromatrix was used on him by his physician.Mdr no: mw5101077, mdr date: 30-apr-2021.Patient alleged that he went to an ent specialist because of nasal dryness.The doctor mixed micromatrix with prp and injected the mixture in his turbinates.Patient claimed that since the treatment, he is suffering from heart discomfort, dysautonomia, dizziness, gi disturbances and itching.Additionally, post procedure testing revealed dysautonomia, hypertension (previously patient stated he was hypotensive) and weight gain.Integra/ acell and complainant had a phone conversation on (b)(6) 2021 and some additional information was obtained: - date of procedure is (b)(6) 2021 and not (b)(6) 2021 as specified in the medwatch report earlier submitted by the patient.- name and address of the ent specialist who performed the treatment is: dr.(b)(6), md.(b)(6).- patient is 47 year old, white male.- patient suffered from dry nose syndrome and rhinitis prior to treatment - complainant claimed that the patient did not have pre-existing medical condition similar to adverse event he is now experiencing.- patient family medical history does not include diabetes, hypertension, heart arrhythmias' or other symptoms similar to the adverse event.- patient is allergic to dust and mold, but does not know whether he is allergic to porcine.- complainant also added extreme palpitation as one of the adverse effects in addition to the mentioned earlier in the medwatch report.- the patient has contacted third party doctors/ specialists for the remedial treatment of adverse effect.List of medications include propanolol, quercetin, magnesium, vitamin c, vitamin d - a sampling of email exchanges between the doctor and the complainant were provided to integra/acell by the complainant.As per the email exchanges, the mixture that was injected in the complainant's turbinates' consisted of 3ml prp + 100mg micromatrix.In one of the emails doctor seems to describe micromatrix as "an fda approved protein to enhance wound healing".Patient's lifestyle habits are unknown.

Search Alerts/Recalls

New Search | Submit an Adverse Event Report

Brand Name	MICROMATRIX
Type of Device	MICROMATRIX
Manufacturer *(Section D)*	ACELL, INC. 6640 Eli Whitney Drive Columbia MD 21046
MDR Report Key	11982214
MDR Text Key	255644907
Report Number	3005920706-2021-00002
Device Sequence Number	1
Product Code	KGN
Combination Product (y/n)	N
PMA/PMN Number	K172399
Number of Events Reported	1
Summary Report (Y/N)	N
Report Source	Manufacturer
Source Type	Other
Type of Report	Initial,Followup
Report Date	06/23/2021
***1* Device was Involved in the Event**	
***1* Patient was Involved in the Event**	
Is this an Adverse Event Report?	Yes
Is this a Product Problem Report?	No
Device Operator	Health Professional
Device Model Number	MICROMATRIX
Was Device Available for Evaluation?	No
Initial Date Manufacturer Received	05/20/2021
Initial Date FDA Received	06/11/2021
Supplement Dates Manufacturer Received	05/20/2021
Supplement Dates FDA Received	06/25/2021
Is This a Reprocessed and Reused Single-Use Device?	No
Patient Sequence Number	1
Patient Outcome(s)	Other;
Patient Age	47 YR